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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,832	11/03/2005	Gactan Terrasssc	N/A	2502

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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	**PAPER NUMBER**
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,832	TERRASSSE ET AL.	
	Examiner	Art Unit	
	Helen Nguyen	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 12/08/2006. Amendments to the specification are accepted. Claims 1-20 are cancelled. **Claims 21-40** are new and remain pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the concentric crowns having eight points equally distributed with four points to each crown angularly positioned in alternation of **Claims 28-30** must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 21-25, 27, 31-33, 35, 37-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al (US Pat No. 5139029) in view of Baldo et al (US Pat No. 5099857).

5. In regards to **Claim 21**, Fishman et al disclose a cutaneous diagnostic kit comprising:

At least a central body (241) having an upper surface mounted to a single body of gripping and pressure, a lower surface having a sharp edge on the external surface, best seen in Figure 18 near reference numeral 220, a cavity being disposed around a central axis of the central body and having a lower end extending beyond the horizontal plane of the sharp edge, best seen in Figure 18, a multipoint needle assembly (Col.13: 46-47) best seen in Figure 37 mounted to the cavity, a flexible ring or "spring portion" (210) having an inner edge defined as a top portion mounted around the central body and an outer edge defined as a lower portion held by a rigid support (200), and at least an allergen (160) composition filled in the cavity and the surrounding space near the lower surface of the flexible ring and the central body, wherein the

cavity is defined as the area from the top portion to about halfway to where said allergen resides and contacting said allergen and the surrounding space is defined as the remaining portion contacting said allergen to the bottommost point, wherein said allergen is contained within said cavity and thus constitutes filled as such.

6. However, Fishman et al do not disclose a blister fixed on the support and the lower surface of the central body. Baldo et al disclose a blister or "bottom layer" (9), best seen in Figures 1-3, fixed on a support and the lower surface of a central body of an analogous cutaneous diagnostic kit for ensuring the sterility of the diagnostic kit prior to use. Therefore, it would have been obvious to one of ordinary skill in the art to include such a blister as taught by Baldo et al fixed on to the support and the lower surface of the central body of Fishman et al to maintain device sterility prior to use.

7. In regard to **Claims 22-24**, Fishman et al disclose a plurality of substantially identical central bodies, namely three, best seen in Figure 15, wherein each of the central body is separated by a different distance (Col.6: 47-59).

8. In regards to **Claim 25**, Fishman et al disclose each of the central body separated by a distance but do not specify the distance. Baldo et al disclose an analogous cutaneous diagnostic device wherein the distance between a first and second central body is about 1 cm to 3 cm and the distance between a second and third central body is about 2 cm to 4 cm, wherein Baldo et al disclose a minimum of 20 mm (2 cm) between separate units for most effective use (Col. 2: 61-63). Therefore, it would have been obvious to one of ordinary skill in the art to modify the

device of Fishman et al such that the distance between a first and second central body is about 1 cm to 3 cm and the distance between a second and third central body is about 2 cm to 4 cm, as taught by Baldo et al, as an effective distance between central bodies during use.

9. In regards to **Claim 27**, Fishman et al disclose the multipoint needle assembly is fixed on at least a crown, best seen in Figure 37.

10. In regards to **Claim 31-32**, Fishman et al disclose the allergen composition but do not disclose said allergen in liquid gel form. Baldo et al disclose allergen composition in the convenient form of gel for use (Col.2: 64-66). Therefore, it would have been obvious to one of ordinary skill in the art to modify the allergen composition of Fishman et al to be in the form of liquid gel for convenience of use.

11. In regard to **Claims 33, 35, and 37**, Fishman et al disclose the allergen composition comprises a mixture of pollens' allergens, food allergens, and domestic environmental allergens (Col.1: 25-26).

12. In regards to **Claim 40**, Fishman et al disclose each central body capable of containing different allergen compositions.

13. In regard to **Claims 38-39**, Fishman et al disclose the testing of domestic environmental allergens including animal dander (Col.1: 25-26) but do not specify specific types of allergens.

However, it is obvious to one of ordinary skill within the art that specifically identified allergens may be tested, and that any of such allergens may be tested, such that it would be obvious to one of ordinary skill within the art to test allergens such as acarid's allergens, superficial body growth of dog and cat and molds, and tropomyosines, profilines, and cystine proteases.

14. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al in view of Zeytinoglu et al (US Pat No. 5874226). Fishman et al disclose said cutaneous diagnostic kit but are silent as to the dimensions of said cavity. Zeytinoglu et al disclose a skin testing device comprising a cavity, referred to as "retainer" (1), that is preferably 0.5 cm high to enable proper containment of test agents, best seen in Figure 1 (Col.3, line 1-4, 46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fishman et al such that said cavity has a height ranging between 0.2 centimeter and 1 centimeter as taught by Zeytinoglu for optimal containment of test agents and functioning.

15. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al in view of Trautman et al (US Pat No. 6083196). Fishman et al disclose the multipoint needle assembly above but do not disclose a plurality of concentric crowns. Trautman et al disclose a transdermal device comprising needle points, referred to as "microprotrusions" (4), arranged on at least two concentric crowns such that said configuration enables sufficient area for agent holding, best seen in Figure 7 (Col.7, line 42-50). Therefore, it would have been obvious to one of ordinary skill in the art to modify the multipoint needle assembly of Fishman et al to be fixed

to a plurality of concentric crowns as taught by Trautman et al, to increase effective agent holding during use of the device.

16. **Claims 29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al in view of Trautman et al, further in view of Pitesky (US Pat No. 6258041). Fishman et al disclose said cutaneous diagnostic kit described above but do not disclose said multipoint needle containing eight points equally distributed and fixed on two crowns with four points to each crown. Pitesky discloses an allergy testing device using a needle with preferably eight points, referred to as "tines" (32) (Col.4, line 52-56), best seen in Figure 8, for the most satisfactory test results (Col.10, line 7-11). As Trautman et al already disclose needle points equally arranged on two concentric crowns and angularly positioned in alternation for the reasons stated above, it would have been obvious to one of ordinary skill in the art to modify the multipoint needle assembly of Fishman et al as modified by Trautman et al to contain eight points as taught by Pitesky equally distributed on two concentric crowns, four points on each crown, to provide the best configuration for optimal testing results.

17. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al in view of Holm et al (US Pub No. 20030175312), Palacios Pelaez et al (WO 98/59052), and Vogel et al (US Pat No. 6864404). Fishman et al disclose said cutaneous diagnostic kit for patient's atopy testing pollens allergens but do not specify the type of pollen allergen. Holm et al teach that PR-10 proteins may be possible allergens (¶0392), Palacios Pelaez disclose profiline as a plant allergen (abst), and Vogel et al disclose that pectate lyase are also possible human allergens

(Col.1, line 51-52). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Fishman et al such that PR10, profilines, and pectate lyase, as taught by Holm et al, Palacios Pelaez et al, and Vogel et al respectively, are tested for as possible allergens.

18. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al in view of Lusk et al (US Pat No. 6423546). Fishman et al disclose said cutaneous diagnostic kit for patient's atopy for testing food allergens but do not identify specific allergens to be tested. For example, Lusk et al teach that lipid transfer proteins as potential food allergens (Col.8, line 13-14) and should be tested on individuals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fishman et al to include testing of specific food allergens, such as lipid transfer proteins, as taught by Lusk et al, as well as any other specific allergens including chitinases, as possible allergens during device use.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
1/22/2007